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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,737

01/29/2004

Roney Graf

33901/US

5736

25763

7590

03/30/2010

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EXAMINER

PATEL, PRITESH ASHOK

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

03/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/767,737	Applicant(s) GRAF ET AL.	
	Examiner PRITESH PATEL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/21/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/03/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-21 and 36-40 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Harris (U.S. Patent No. 5226895) in view of Buch-Rasmussen et al. (U.S. Patent No. 6582408 B1).
3. Concerning claims 1, 18, 36, 37, and 40, Harris discloses in figures 1 and 2, an injection apparatus comprising a reservoir module having a front casing section (12) which comprises a disposable reservoir (14) a blocking means (71); a first connecting means, (19), comprising a first latching element; a piston (36); a piston rod (56) which comprises a returning blocking means (66), located on the surface of the piston rod (64), comprising a row of serrated teeth which prevent the piston rod from rotating relative to the front casing section; a dosing and activating module comprising a rear casing (86 and 100) which comprises a second connecting means (94), comprising a second latching element; a dosing and drive device (72); and a dosage setting member (104) which is moved by the dosing and drive device and which engages with the piston rod; wherein the connecting means form an axial linear guide. Harris fails to disclose an axial guide on a casing of the apparatus. Buch-Rasmussen et al. discloses means for coupling the dosing assembly and the cartridge assembly, respectively rear and front casings, as being a series of mechanisms including bayonet locks, long protruding elements that can axially align two

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casings (Column 3, Lines 8-14).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris by incorporating multiple axial alignments in the form of multiple bayonet locks as taught by Buch-Rasmussen et al. It would have been further obvious to have a dosage setting member settable while a piston remained still to have accurate dosing and that reusable and disposable sections of casing are common in the art.

Concerning claims 2, 3, 4, 5, 6, 7, and 8, Harris fails to disclose axial guides and variations of the sort. Buch-Rasmussen et al., as disclosed above limitation, he discloses the use of bayonet locks to connect the front and rear casings. The disclosure also allows for multiple locks and all variations of bayonet locks (Column 3, Lines 8-14). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris by using bayonet locks as taught in Buch-Rasmussen et al. as axially aligned elements. It would have been further obvious to one of ordinary skill in the art at the time of the invention that there are many variations of a bayonet lock and that counterparts of the axial guides will be on an opposite casing section to the casing section containing the axial guides.

4. Concerning claims 9,10,11,12,13, 14, 15, 16, 17, 19, 20, and 21, and in addition to the above disclosure, Harris discloses in Figures 4 and 5 the dosage setting member (104) engaging with the rear casing section (86 and 100) in pre-set rotational angular positions so as to be linearly and axially guided, wherein a locking projection (106) and a locking recess (104) are in locking engagement and can be moved by a restoring

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elasticity force. Harris discloses in Figure 7 the dosing and drive device (72) and the piston rod (56) engaging with each other. Harris discloses in Figures 5 and 9 the dosing movement being a rotational movement about a threaded longitudinal axis of the piston rod. Harris does not disclose an axial guide that aligns the two casing sections. Buch-Rasmussen et al. discloses an axial guide as described in the above disclosure (Column 3, Lines 8-14).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris with bayonet locks on the casing sections as taught by Buch-Rasmussen et al.

5. Concerning claim 38, Harris discloses the front and rear casing sections, a piston, a piston rod, a disposable casing section, and a dosage setting mechanism, and other components as listed above (Refer to Figures as indicated above). Harris does not disclose an alignment mechanism or a removable cartridge with a piston. Buchman-Rasmussen et al. discloses bayonet locks, generally axially aligned, and a removable cartridge that contains a piston.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris with bayonet locks and a removable cartridge with a piston as taught by Buchman-Rasmussen et al. The previous disclosure in this action also meets the limitation of Claim 38 of the patent application.

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Concerning claim 39, it would have been obvious to one of ordinary skill in the art at the time of the invention that a driven member or piston would be secured against rotation by a mechanism, as piston's are commonly only longitudinally movable in the art.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./

Examiner, Art Unit 3763

03/26/2010

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763